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*Attorneys for Defendant Merck & Co., Inc.*

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
IN RE: :  
Fosamax Products Liability Litigation : 1:06-md-1789 (JFK)  
:  
-----X  
*This Document Relates to:* : **ANSWER AND AFFIRMATIVE  
Charlette Burns; and DEFENSES OF MERCK  
Coye Holman, & CO., INC.;  
Jointly and Severally  
v. Merck & Co., Inc. DEMAND FOR JURY TRIAL  
:  
Case No: 1:08-cv-1803-JFK :  
-----X**

Defendant, Merck & Co., Inc. (“Merck”), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

**CASE DISCOVERY**

The allegations of the first sentence of the Case Discovery paragraph do not require a response. Merck denies the remaining allegations of the Case Discovery paragraph, except that for jurisdictional purposes only, admits that the Plaintiffs seek damages in excess of \$75,000.00.

**STATEMENT OF PARTIES**

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1.

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.

3. Merck denies each and every allegation of Paragraph 3, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey, and that it is registered to do business in the State of Texas, and that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

**JURISDICTION**

4. The allegations of the first sentence of Paragraph 4 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 4, except that for jurisdictional purposes only, admits that the Plaintiffs seek damages in excess of \$75,000.00. Merck denies the remaining allegations of Paragraph 4.

**VENUE**

5. The allegations of Paragraph 5 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 5, except Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegation that Plaintiffs resided in Jefferson County.

6. The allegations of the first and second sentences of Paragraph 6 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first and second sentences of Paragraph 6. Merck denies the allegations of the third sentence of Paragraph 6, except that it is without knowledge as to whether Plaintiffs ingested FOSAMAX®.

### **FACTS**

7. Merck denies each and every allegation of Paragraph 7.
8. Merck denies each and every allegation of Paragraph 8.
9. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 9.
10. Merck denies each and every allegation of Paragraph 10.
11. Merck denies each and every allegation of Paragraph 11.
12. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 12. Merck denies allegations of the second sentence of Paragraph 12.
13. Merck denies each and every allegation of Paragraph 13.

### **THEORIES OF RECOVERY**

#### **A. Count I: Strict Products Liability**

14. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

15. Merck denies each and every allegation of Paragraph 15, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

16. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first sentence of Paragraph 16. Merck denies the allegations of the second sentence of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

**B. Count II: Negligence**

22. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

23. Merck denies each and every allegation of Paragraph 23.

**C. Count III: Misrepresentation And Fraud**

24. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

**D. Count IV: Civil Conspiracy And Commercial Bribery**

29. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

30. Merck denies each and every allegation of Paragraph 30.

**E. Count V: Breach Of The Implied Warranty Of Merchantability**

31. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of the first and second sentences of Paragraph 33, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the third sentence of Paragraph 33.

34. Merck denies each and every allegation of Paragraph 34.

**F. Count VI: Breach Of The Implied Warranty Of Fitness For A Particular Purpose**

35. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck is without knowledge as to what is meant by the phrase "actually and/or constructively," so the allegations in Paragraph 37 are denied.

38. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

**G. Count VII: Breach of Express Warranty**

40. Merck repleads its answers to all other paragraphs of the Complaint, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

41. Merck denies each and every allegation of Paragraph 41, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

**H. Count VIII: Gross Negligence/Malice**

42. Merck denies each and every allegation of Paragraph 42.

**AGENCY**

43. Merck denies each and every allegation of Paragraph 43.

**CAUSATION**

44. Merck denies each and every allegation of Paragraph 44.

**DAMAGES**

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54, except that for jurisdictional purposes only, admits that the Plaintiffs seek damages in excess of \$75,000.00.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

**UNCONSTITUTIONAL PROVISIONS OF TEXAS LAW**

58. The allegations of the first phrase of Paragraph 58 regarding provisions on which Defendant may “attempt[] to rely” do not require a response. The remaining allegations of Paragraph 58 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies the remaining allegations of

Paragraph 58, including the allegations contained in subparts (a) through (e), and respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

**JURY DEMAND**

59. The allegations of Paragraph 59 do not require a response.

**PRAYER**

Merck denies that Plaintiffs are entitled to any of the relief requested in their Prayer, including each and every request contained in subparts (a) through (g).

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

**FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and

potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned.

**EIGHTH AFFIRMATIVE DEFENSE**

The injuries and damages, if any, sustained by the Plaintiffs resulted in whole or in part from their own comparative negligence and any damages recovered should be reduced accordingly.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiffs' misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the

product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Texas, Mississippi, and New York Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims of fraud are not pleaded with the required particularity.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

The substantive law of Texas applies to Plaintiff Charlette Burns' claim.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

If Plaintiff Burns sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiff Burns and/or of third parties, not from any negligence or breach of duty by

Merck. If judgment is rendered in Plaintiff Burns' favor, the amount of such judgment must be reduced pursuant to the Proportionate Responsibility Statute § 33.001, et seq. of the Texas Civil Practice & Remedies Code.

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

Merck is unaware at this time of any settlements by any alleged joint tortfeasor. In the event any settlement is or has been made by any alleged joint tortfeasor, however, then Merck is entitled to a full credit, offset, pro rata reduction, or percentage reduction, based on the percentage of fault attributable to each settling party, person, or other entity herein, and Merck makes known to the other parties and to the court that it will avail itself of its rights under §§ 33.012 et seq. of the Texas Civil Practice & Remedies Code.

**FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Merck fully asserts § 82.001 and § 82.007 of the Texas Civil Practice and Remedies Code and states that all of Plaintiff Burns' claims are barred under those sections.

**FORTY-NINTH AFFIRMATIVE DEFENSE**

To the extent Plaintiff Burns is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**FIFTIETH AFFIRMATIVE DEFENSE**

Any claims for exemplary damages are limited by Section 41.008 of the Texas Civil Practice and Remedies Code to two times the amount of actual damages or \$200,000, whichever is greater. Merck asserts all other defenses and limitations on

punitive damages contained in Chapter 41 of the Texas Civil Practice and Remedies Code.

**FIFTY-FIRST AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law without proof of every element beyond a reasonable doubt would violate Merck's rights under Amendments IV, V, VI and XIV of the United States Constitution and under Sections 9, 10, 14 and 19 of Article I of the Texas Constitution.

**FIFTY-SECOND AFFIRMATIVE DEFENSE**

Unless Merck's liability for punitive damages and the appropriate amount of punitive damages are each required to be established by clear and convincing evidence under Texas law, any awards of punitive damages would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-THIRD AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because any award of punitive damages under Texas law without bifurcating the trial as to all punitive damages issues would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-FOURTH AFFIRMATIVE DEFENSE**

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law subject to no pre-determined limit, either a

maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-FIFTH AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law by a jury that:

- (1) is not provided any standard of sufficient clarity for determining the appropriateness, or the appropriate size of any punitive damages award;
- (2) is not instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment;
- (3) is not expressly prohibited from awarding punitive damages or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics;
- (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; or
- (5) is not subject to judicial review on the basis of objective standards would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-SIXTH AFFIRMATIVE DEFENSE**

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law for the purpose of compensating Plaintiff

Burns for elements of damages not otherwise recognized by Texas law would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

**FIFTY-SEVENTH AFFIRMATIVE DEFENSE**

Merck asserts that the determination of the amount of punitive damages, if any, shall be bifurcated from the remaining issues pursuant to *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994).

**FIFTY-EIGHTH AFFIRMATIVE DEFENSE**

The imposition of punitive damages violates the open courts provision of the Texas Constitution.

**FIFTY-NINTH AFFIRMATIVE DEFENSE**

The substantive law of Mississippi applies to Plaintiff Coye Holman's claim.

**SIXTIETH AFFIRMATIVE DEFENSE**

Merck affirmatively pleads Miss. Code § 85-5-7 (1972), as amended by Miss. Laws 2003, 3rd Ex. Sess., Ch. 2 § 4, effective January 1, 2003.

**SIXTY-FIRST AFFIRMATIVE DEFENSE**

To the extent that Plaintiff Holman's claims are based upon any theory of product liability, they are barred or limited by Mississippi's Product Liability Act, Miss. Code § 11-1-63 (1972), as amended by Miss. Laws 2004, 1st Ex. Sess., Ch. 1 § 3, effective September 1, 2004.

**SIXTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff Holman's claims for non-economic damages are subject to and limited by Miss. Code § 11-1-60 (1) (a) through (c) (1972), as amended by Miss. Laws 2004, 1st Ex. Sess., Ch. 1 § 2, effective September 1, 2004.

**SIXTY-THIRD AFFIRMATIVE DEFENSE**

Should Merck be held liable to Plaintiff Holman, which liability is specifically denied, Merck would be entitled to a set off for the total of all amounts paid to Plaintiff Holman from all collateral sources.

**SIXTY-FOURTH AFFIRMATIVE DEFENSE**

Some or all of the damages alleged by Plaintiff Holman are barred by Miss. Code §§ 75-2-714, 715 (1972).

**SIXTY-FIFTH AFFIRMATIVE DEFENSE**

Notwithstanding the claims and contentions of Plaintiff Holman, he received all or substantially all of the benefit from FOSAMAX® that he hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiff Holman might be entitled to recover from Merck must be correspondingly reduced.

**SIXTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff Holman's claim for any punitive damages against Merck fails under Miss. Code § 11-1-65 (1972), as amended by Miss. Laws 2004, 1st Ex. Sess., Ch. 1 § 4, effective September 1, 2004.

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Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and

equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees as may be available by law, together with such and other and further relief that the Court may deem just and proper.

**JURY DEMAND.**

Defendant hereby demands a trial by jury.

DATED:      New York, New York  
                  March 24, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: \_\_\_\_\_ /s/

Norman C. Kleinberg

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*Attorneys for Defendant Merck & Co., Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 24<sup>th</sup> day of March, 2008, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

LAMINACK, PIRTLE & MARTINES  
Richard N. Laminack  
Thomas W. Pirtle  
Buffy K. Martines  
440 Louisiana, Suite 1250  
Houston, Texas 77002

The above addresses have appeared on the prior papers in this action as the office address of the attorneys for Plaintiff.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on March 24, 2008

/s/  
Shawn McEnnis